AUG 0 2 2002

K012105

510(k) Summary Pursuant to 21 CFR 807.92

1. Submitted By: PolyVac Inc.
253 Abby Road
Manchester, New Hampshire 03103

2. Contact: D. Darin Martin, Official Correspondent for PolyVac Inc. at:
Symmetry Medical Inc.
220 West Market Street
Warsaw, Indiana 46582

3. Product: PolyVac Surgical Instrument Delivery System
880.6850 Sterilization Wrap
Class II
Pack, Sterilization Wrapper, Bag and Accessories
80 KCT

4. Common Names:

Minitainer	Modultainer IV
Instrument Cassettes	Opitainer
Standard Modultainer	Universal
Modultainer II	Modultainer III
Modultainer II Hybrid	Vault
LapCare /Arthrocare	

Description:

PolyVac Delivery Systems consist of different sizes of the same basic configuration. All systems consist of a minimum of a plastic or metal base and lid. All lids can be fastened to the base by means of assembled hardware or by a locking tab, designed as part of the lid. Accessories may be used with systems to organize or separate contents to be placed in them for use.

The Delivery Systems are designed using plastic and metal materials that can be reused with steam sterilization methods. Each tray and lid has an evenly distributed hole pattern in relation to its size.

Intended Use:

PolyVac's delivery systems are intended to protect medical device instrumentation and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with an approved sterilization wrap, sterility of the enclosed medical device is maintained until used.

PolyVac's delivery systems are to be sterilized in one of the following cycles:

Prevacuum Steam : 132°C - 4 minutes minimum
Dry for 20 – 40 minutes as needed

Gravity Steam: 132°C - 30 minutes minimum
Gravity Steam: 121°C - 55 minutes minimum
Dry for 20 – 50 minutes as needed

Technological Characteristics:

The PolyVac Delivery System does not incorporate any new technological characteristics or material as compared to legally marketed devices.

Performance Data:

A summary of the following testing is provided to support the premarket notification:

Acute Systemic Toxicity USP: Extracts of test article injected into mice did not produce a significantly greater systemic reaction than the blank extractant.

Intracutaneous Toxicity USP: Extracts of test article injected intracutaneously into rabbits did not produce a significantly greater tissue reaction than the blank extractant.

Implantation Test USP: The macroscopic reaction of the test article implanted 7 days was not significant as compared to the USP negative control plastic.

Sterilization Qualification: The test articles were inoculated with a biological indicator organism, and thermocouples were placed. They were then wrapped in a double layer of approved sterilization wrap and placed into the sterilizer for processing. The system was successfully sterilized in a Prevacuum Cycle at 132°C for a 2 minutes (4 minute ½ cycle), a Gravity air Displacement Cycle at 132 °C for 15 minutes (30 minute ½ cycle), and a Gravity air Displacement Cycle at 121 °C for 27.5 minutes (55 minute ½ cycle). The sterilization tests demonstrated a six log reduction of all spores strips and inoculated devices. Thermocouple data indicated excellent steam penetration within the wrapped packages.

Substantial Equivalence:

The Delivery Systems offered by PolyVac are comparable in design to sterilization cases and trays manufactured by Riley Medical #K944025 (primary predicate).

Additionally, sterilization cases and trays are also offered by:

Tuttnauer USA	#K990761
C/T Medical Systems	#K980065

Conclusions:

The studies conducted on PolyVac's Delivery Systems demonstrate that the device is substantially equivalent to other sterilization cases and trays currently in commercial distribution. Additionally, it provides a reliable means of packaging, transporting, and storing instruments for sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 2 2002

Mr. D. Darin Martin
Vice President, Quality Assurance & Regulatory Affairs
Symmetry Medical, Incorporated
220 West Market
Warsaw, Indiana 46580

Re: K012105
Trade/Device Name: PolyVac Surgical Instrument Delivery System
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: June 4, 2002
Received: June 5, 2002

Dear Mr. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Susan Runner

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K012105

Device Name: PolyVac Surgical Instrument Delivery System

Intended Use: PolyVac's delivery systems consist of perforated trays with lids, which are intended to enclose and protect medical device instrumentation, and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with an approved sterilization wrap, sterility of the enclosed medical device is maintained until used.

PolyVac's delivery systems are to be sterilized in one of the following cycles:

- Prevacuum Steam : 132°C - 4 minutes minimum
  Gravity Steam: 132°C - 30 minutes minimum
  Gravity Steam: 121°C - 55 minutes minimum

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ or Over-the-counter use ___
(Per CFR 801.109)

Elaine S. Lim

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012105